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Fitness Check of the EU legislation with regard to Endocrine Disruptors - Stakeholders Survey

Fields marked with * are mandatory.

Introduction

Scope and objectives

In its Communication 'Towards a comprehensive European Union framework on endocrine disruptors', adopted on 7 November 2018, the Commission confirmed its commitment to protect EU citizens and the environment from endocrine disruptors by minimising human and wildlife exposure to these substances. The Communication outlines a comprehensive set of actions including a cross-cutting Fitness Check of the relevant legislation.
The Fitness Check aims at analysing the coherence of the different regulatory approaches to the assessment and management of endocrine disruptors and at assessing whether legislation delivers on its objectives to protect humans and the environment.
The legislative measures constituting the EU legal framework regulating chemicals have been developed at different points in time and have, in certain cases, different objectives. This has resulted in different approaches to regulating endocrine disruptors, depending on the sector, and has raised questions as to whether the EU legal framework regulating endocrine disruptors is sufficiently coherent. The Fitness Check aims to assess specifically the consequences of the absence of common criteria to identify endocrine disruptors across the different legal frameworks, and different regulatory approaches for managing substances identified as endocrine disruptors. More information is available in the published Roadmap.
Stakeholder consultation is an essential step to collect evidence for the Fitness Check. It aims at gathering inputs from a broad range of stakeholder groups as well as citizens to ensure that relevant evidence and views from all interested parties are considered in the evaluation. The consultation activities solicit input to the analysis of the coherence of the EU framework, as well as, to the extent possible, its effectiveness, efficiency, relevance and EU added value.

The aims of this stakeholder survey are:

- To collect views on possible legislative inconsistencies and to assess their impact on stakeholders;
- To collect information from stakeholders on the effectiveness of the current EU legislation for the identification and risk management of endocrine disruptors;
- To collect information on the efficiency of procedures for the identification and risk management of endocrine disruptors (e.g. duplication of efforts) and to identify opportunities for improvement.

Target audience

This survey is addressed to **stakeholder organisations** such as businesses, public authorities, academia research and NGOs, and to **experts** working in such areas responding in their professional capacity. If you would like to comment in your personal capacity from a citizen's perspective, please respond to the public survey.

Instructions

Respondents are encouraged to explain their answers providing examples and data in the open fields provided. However, there is no mandatory field in the main survey section.
Answers should be in **English**.

Information on respondent

* I am giving my contribution as:

Some questions are specific to certain stakeholders group(s) and will be visible according to your answer to this question

- ( ) Academic/research institution
- ( ) Business association
- ( ) Company/business organisation
- (•) Civil society organisations
- ( ) Public authority
- ( ) Trade union
- ( ) Other

* First name

50 character(s) maximum

Apolline

* Surname

50 character(s) maximum

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* Organisation name

50 character(s) maximum

ClientEarth

Country of origin of your organisation

- ○ Austria
- ◉ Belgium
- ○ Bulgaria
- ○ Croatia
- ○ Cyprus
- ○ Czechia
- ○ Denmark
- ○ Estonia
- ○ Finland
- ○ France
- ○ Germany
- ○ Greece
- ○ Hungary
- ○ Ireland
- ○ Italy
- ○ Latvia
- ○ Lithuania
- ○ Luxembourg
- ○ Malta
- ○ Netherlands
- ○ Poland
- ○ Portugal
- ○ Romania
- ○ Slovak Republic
- ○ Slovenia
- ○ Spain
- ○ Sweden
- ○ United Kingdom
- ○ Other (Please specify)

* Scope

- ◉ International
- ○ National
- ○ Regional
- ○ Local

* Organisation size

- ○ Micro (1 to 9 employees)
- ○ Small (10 to 49 employees)
- ◉ Medium (50 to 249 employees)
- ○ Large (250 or more)

* **Publication privacy settings**

The Commission will process the responses of this stakeholders survey for the purpose of the Fitness Check on the EU legislation on endocrine disruptors. This includes the publication of a summary report of the survey. You can choose to give your consent to publish your personal details, or to remain anonymous.

- ○ **Anonymous** - Only your stakeholder group, country of origin, sector, scope and size of your organisation may be published. Your personal details will not be published.
- ◉ **Public** - Your personal details may be published with your contribution.

☑ I agree with the following personal data protection provisions

Personal data protection provisions

Privacy_statement.pdf

Survey

1) How familiar are you with the following pieces of legislation?

	Not at all familiar	A little familiar	Fairly familiar	Very familiar
Plant Protection Products Regulation (EC) 1107/2009	○	○	○	◉
Residues of Pesticides Regulation (EC) 396/2005	○	○	◉	○
Biocidal Products Regulation (EU) 2012/528	○	○	○	◉
REACH Regulation (EC) 1907/2006	○	○	○	◉
CLP: Classification, Labelling and Packaging of substances and mixtures (EC) 1272/2008	○	○	○	◉
Persistent Organic Pollutants Regulation (EC) 850/2004 and (EU) 2019/1021	○	○	◉	○
Food Contact Materials Regulation (EC) 1935/2004	○	○	○	◉
Contaminants in Food and Feed Regulation (EEC) 315/93 and Directive (EC) 32/2002	○	◉	○	○
Food Additives Regulation (EC) 1333/2008	○	◉	○	○
Cosmetic Products Regulation (EC) 1223/2009	○	○	○	◉
Medical Devices Regulation (EU) 2017/745	○	◉	○	○
In vitro Diagnostic Medical Devices Regulation (EU) 2017/746	○	◉	○	○
Toy Safety Directive 2009/48/EC	○	○	○	◉
Fertilisers Regulation (EC) 2003/2003 and Regulation (EU) 2019/1009	◉	○	○	○
Detergents Regulation (EC) 648/2004	○	○	◉	○

Medicinal Products for Humans Directive 2001/83/EC	○	◉	○	○
Veterinary Medicinal Products Regulation (EU) 2019/6	○	◉	○	○
General Product Safety Directive 2001/95/EC	○	○	○	◉
Water Framework Directive 2000/60/EC	○	○	◉	○
Priority Substances Directive 2013/39 EC	○	◉	○	○
Drinking Water Directive 98/83/EC	○	○	◉	○
Groundwater Directive 2006/118/EC	○	○	◉	○
Marine Strategy Framework Directive 2008/56/EC	○	○	◉	○
Urban Waste Water Directive 91/271/EEC	○	◉	○	○
Chemical Agents at Work Directive 98/24/EC	◉	○	○	○
Carcinogens and Mutagens at Work Directive 2004/37/EC	◉	○	○	○
Pregnant Workers Directive 92/85/EEC	◉	○	○	○
Young People at Work Directive 94/33/EC	◉	○	○	○
Waste Directive 2008/98/EC	○	○	◉	○
Restriction of the use of certain hazardous substances in Electrical and Electronic Equipment - Directive 2011/65/EU	○	○	○	◉
Industrial emissions Integrated Pollution Prevention and Control Directive 2010/75/EU	○	○	◉	○
Seveso-III-Directive 2012/18/EU	○	○	◉	○
Ambient Air Quality and Cleaner Air for Europe Directive 2008/50/EC	○	○	◉	○
Regulation (EC) 66/2010 on the EU Ecolabel	○	○	○	◉

Horizontal approach to the identification of endocrine disruptors

Recently the European Commission published criteria for the identification of endocrine disruptors under both the Biocidal Products Regulation and the Plant Protection Products Regulation, which were very similar to each other and based on the WHO definition [1]. Other pieces of EU legislation related to human health and environmental protection from manufactured chemicals do not contain such criteria.

[1] "*An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations*."

2) To what extent does the absence of harmonised criteria pose a problem to a coherent approach for the **id entification** of endocrine disruptors?

- ◉ It is an important problem, leading to incoherent identification of endocrine disruptors across sectors

- ○ It is not a problem, the criteria should be sector specific

Please explain your answer, indicating the sector(s) in which this problem occurs (max 1000 characters)

1000 character(s) maximum

A minority of EU laws requires substance testing. These Regulations (REACH, PPPR, BPR, Detergents and some substances in cosmetics and FCM) need harmonized criteria that would adapt the WHO/IPCS definition as interpreted by the 2013 JRC report to recognize the policy relevance of suspected as well as known EDCs. It is the only way to manage data scarcity, and could be done via implementation guidance

The others (Waste, water, worker protection, product regulations) rely on an internal list of substances of concern and/or a list set in another EU law. The priorities are:
- Catch up: Add currently known and suspected EDCs to their internal list of dangerous substances- EDCs identified in EU and national list and regulations
- Responsiveness: add a provision that automatically submits the EDCs identified or regulated in EU horizontal (REACH, CLP, new one) or other sectoral (PPPR, FCM) laws to their provisions controlling dangerous substances in general or EDCs in particular

The Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) set rules for the classification and labelling of hazardous substances, based on their physical, health or environmental hazards.

3) Do you think that the lack of a hazard category covering endocrine disrupting properties in the CLP Regulation and/or GHS poses a problem for the coherent **identification** of endocrine disruptors?

- ○ Yes
- ◉ No

4) Do you think that the lack of a hazard category covering endocrine disrupting properties in the CLP Regulation and/or GHS poses a problem for the coherent **risk management** of endocrine disruptors?

- ○ Yes
- ◉ No

Please explain your answers to questions 3 and 4, if possible indicating the sector(s) in which this problem occurs.

1000 character(s) maximum

Adding EDCs to GHS is a good long-term goal, internal action must come first, which will protect people and environment during the long international negotiations and strengthen the EU's negotiating position
Adding EDCs to CLP would facilitate their identification and management but:
- only if the structural weaknesses that undermine the self-classification and CLH processes (see non-REACH Fitness check and ECHA's reports on the functioning of CLP) are fixed
- Integrating EDCs in CLP does not automatically lead to better risk management. Will be necessary to amend the relevant sectoral legislations to attach consequences to the classification (FCM, cosmetic, toys, etc.).
- building a sufficient list of EDC CLH will take time. A transitional regime for the substances already identified in EU or national lists and regulation as EDCs is needed.

There are alternatives to CLP:
- a new identification system dedicated to EDCs
- REACH candidate list -with the change described in 11c

The CLP Regulation applies different approaches to categorise hazards depending on the endpoints, which may include aspects related to severity of effects or strength of evidence. Some stakeholders have suggested to classify endocrine disruptors in one of three categories based on the level of evidence: i.e. known, presumed or **suspected**.

5) Do you think that a category of **suspected** endocrine disruptor should be introduced?

- (●) Yes
- ( ) No

What should be the regulatory consequences of such a category? What would be the consequences for protecting human health and the environment? What would be the economic consequences?

2000 character(s) maximum

CMRs have long been ranked according to the level of evidence available on their properties. It is only logical that the regulation of EDCs, that addresses an equivalent level of concern, were to do the same. Doing so would guarantee a coherent approach to highly hazardous chemicals and make the identification process transparent and accessible for all relevant stakeholders.
This approach is useful, but it is also indispensable. Data scarcity on the EDCs properties of the substances on the market and the lack of testing methods sensitive enough / on all relevant endpoints make the category of suspected EDC an indispensable regulatory tool. As experienced with CMRs, category 2 needs to be used very often and having to wait for a level of evidence consistent with category 1 may cause undue delay in the control of highly hazardous substances, particularly considering that, in most cases, increased evidence confirms the hazard (see EEA- late lessons from early warning II chapter 2 and 27). The first experience in EDC identification under REACH, cosmetics, PPPR and BPR have already confirmed this situation.
Considering the gravity and irreversibility of EDCs' effects, which affect vulnerable population and future generations the most, integrating a category 2 in the management of EDCs is the only way to comply with the precautionary principle.
As it is common for CMR 2, EU law would need to attach strict regulatory consequences to the identification of suspected EDCs, based on the necessity to reduce exposure. The default approach should be prohibition, with sector specific derogation limited to essential uses with minimized exposure or controlled used with negligible exposure. Obligation to share information with the workers, consumers and in the supply chain should systematically apply.
The economic consequences to consider in priority are the ones attached to an insufficient reduction of the exposure to EDCs, considering the extremely high costs for society

Rationale and consequences of different regulatory approaches

Under some pieces of legislation, endocrine disruptors are regulated based on their hazardous properties, whereas under others they are regulated on the basis of risk.

6) Are you aware of any inconsistencies in the way chemicals are **identified and controlled** with regard to endocrine disrupting properties across regulated areas in the EU?

- (●) Yes

No

Please provide examples and describe the consequences.

2000 character(s) maximum

EU law will be consistent when all sectors draw the same political and legal implications from the current state of scientific knowledge:

EU law should apply a rebuttable presumption that EDCs are non-threshold substances
- when submitted to pre-market authorisation, the applicant shall bear the burden of rebutting the presumption. REACH (COM 2016) 814 final, PPPR and BPR apply this approach but not FCM laws or the Detergent Regulation. Even more concerning, the SCCS overstepped its power when presuming that EDCs are threshold substances (SCCS/1544/14), even though EFSA's opinion it referred to as justification affirms that this choice belongs to the risk manager and is beyond its scope -see p 43, EFSA Journal 2013;11(3): 3132
- in all cases, a generic risk assessment shall apply: prohibition with sectoral derogations limited to essential use or uses with no/negligible release. Medical devices, PPPR apply this approach but not, for ex., cosmetics, Toys or food contact materials

A sector specific identification of an EDC shall automatically trigger horizontal consequences
For ex., the identification of BPA as an EDC under REACH shall have automatic consequences in, for ex., workers protection law, food and cosmetic packages
The scope of the consequences needs to be coherent – for ex. banning BPA from baby feeding equipment is not enough to stop the exposure when it remains in paper/cardboard packaging containing food bound to be used for feeding babies

A regulation requiring a process or product to be safe shall require/provide the information needed to assess this safety:
For substances submitted to pre-market authorisation, appropriate data requirements are needed - not yet the case for REACH, PPPR, BPR and far from the case in Detergent, FCM and cosmetics
For products, a list of EDCs, responsive to new scientific knowledge, is needed to help importers /manufacturers. Currently EDCs as a category are not given special attention in any product law.

7.a) In your opinion, how do **hazard-based criteria for identifying** endocrine disruptors in combination with a **hazard-based approach to decision-making** affect the following objectives?

	Very negatively	Negatively	No effect	Positively	Very positively	Don't know
Human health protection	○	○	○	○	◉	○
Environmental protection	○	○	○	○	◉	○
Functioning of the internal market	○	○	○	○	◉	○
Competitiveness and innovation	○	○	○	○	◉	○

7.b) In your opinion, how do **hazard-based criteria for identifying** endocrine disruptors in combination with a **risk-based approach to decision-making** affect the following objectives?

	Very negatively	Negatively	No effect	Positively	Very positively	Don't know
Human health protection	○	◉	○	○	○	○
Environmental protection	○	◉	○	○	○	○
Functioning of the internal market	○	◉	○	○	○	○
Competitiveness and innovation	○	◉	○	○	○	○

Chemicals are managed under different EU regulations according to their uses and the environmental media into which they are released during their life cycle (production, use, recycling/disposal).

8) Are you aware of any gaps or overlaps in the way endocrine disruptors are regulated in the EU?

- (●) Yes
- ( ) No

Please provide examples and describe the consequences.

1000 character(s) maximum

The mechanisms that are supposed to 'discover' the hazardous properties of substances on the market are not capable of catching EDC because they do not require the relevant data (REACH registration, CLP) and because the category of suspected EDCs is not used (REACH Candidate list)
The mechanisms that are supposed to prevent hazardous substances from entering some products do not require appropriate test to discover EDCs, do not use the category of suspected EDC (PPPR, BPR, cosmetics, Detergent), do not address specifically EDCs (FCM) and some positive lists are not updated (FCM)
The only evolving list that may contain ED is REACH SVHCs but only the Ecolabel and Medical Devices Regulations refer to it
The limited list of controlled hazardous substances in products, Waste and water regulations do not contain provisions specific enough to trigger automatic update in light of EDC knowledge, do not approach EDCs as a category and follow an inadequate substance-by-substance approach.

9) Have you experienced issues or problems because endocrine disruptors are regulated differently in the EU compared with non-EU countries?

- (●) Yes
- ( ) No

If yes, please provide examples and describe the consequences.

1000 character(s) maximum

The EU regrettably still practices double standards – chemicals banned in the EU because of their hazard may be produced and sold to non-EU countries (see Pesticides).

This leads not only to risks for the workers, citizens and environment in other countries but also to the banned chemicals coming back via imported produces and products.

This problem of general nature needs to be addressed.

10) Do you have any further comments on the coherence of EU legislation with regard to endocrine disruptors?

2000 character(s) maximum

Some structural weaknesses in the EU Regulation of hazardous substances weigh heavily on the EU's capacity to coherently control EDCs:
As established by the non-toxic environment study, the regulation of chemicals in consumer products is insufficient. Actions are needed:
- Strengthen insufficient regulations (FCM, eco-design, RoHs for ex.) and fill regulatory gaps (FCM paper &

cardboard, women & children sanitary products, childcare equipment). The protection of children is particularly incoherent: for ex. Babies are protected from BPA in baby bottles but not in all the containers of the food they will eat, nor in childcare equipment. The protection also does not extend to foetus as pregnant women are exposed via their food
- End regulatory fragmentation: REACH struggles to capture the environmental impact of substances in FCM and cosmetics, cocktail and aggregated exposures are not addressed. Chemical exposure needs to be addressed in the way it happens
- Fully disclose the chemical composition of materials and products to enable due diligence in the supply chain as well as informed choice for consumers and investors – more and more EDCs will be 'discovered' which will require to know where they are. The improvement of REACH information on use has a role to play in that regard
- Dedicate more resources to enforcement in order to block the flow of non-compliant products in the market
A coherent approach to risk reduction also requires a systematic use of grouping to avoid regrettable substitution that already happened with BPA replaced by other bisphenols
It also requires a better interconnection between chemical, products, waste and environmental (water, soil, air) regulations in order to ensure that the regulations acting downstream (waste, water) help to control the effectiveness of the upstream regulations (REACH, product regulation), and that the latter are in return fully responsive to issues identified downstream (triggering of review provisions, etc.)

Effectiveness in achieving policy objectives

A common goal of EU chemicals legislation is the protection of human and environmental health, by minimising exposure to hazardous chemicals, while at the same time improving the functioning of the internal market, enhancing competitiveness and innovation, and minimising animal testing. Some regulations have specific provisions for the identification and control of endocrine disruptors.

11) Do you agree with the following statements?

11.a) The regulatory process to identify and control substances with endocrine disrupting properties in **Biocidal Products** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	◉	○	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	◉	○	○
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	◉	○	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	◉	○	○
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	○	○	◉
Promoting alternatives to animal testing	○	○	○	○	○	○

Please explain your answers

2000 character(s) maximum

The BPR is with the PPPR the most developed regulatory framework for EDCs and is built on the principle of prohibition with sector-specific derogations.

For the regulatory process to deliver on the objectives of health/environmental protection and prompting innovation, the competent authorities need to:
- give full effect to the precautionary principle by identifying and attaching regulatory consequences to both known and suspected EDCs
- require from the applicants the tests identified by the most sensitive existing methodologies and develop new test methods beyond E,A,T,S – mediated properties
- make full use of research independent from vested interest, including when it does not follow OECD guidelines and GLP
- progressively evolve towards a system where tests are performed by independent laboratories, supervised and ordered by EU agencies and paid via a fund in which all relevant industries contribute. This would raise the credibility of the data and avoid wasting public and private resources by making the data sharable and public.

11.b) The regulatory process to identify and control substances with endocrine disrupting properties in **Plant Protection Products** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	◉	○	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	◉	○	○
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	◉	○	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	◉	○	○
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	◉	○	○
Promoting alternatives to animal testing	○	○	○	○	○	○

Please explain your answers

2000 character(s) maximum

Same remark as for BPR (11 b)

11.c) The regulatory process to identify and control substances with endocrine disrupting properties under **REACH** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	◉	○	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	◉	○	○
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	◉	○	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	◉	○	○
Improving the functioning of the internal market	○	○	○	◉	○	○
Enhancing competitiveness and innovation	○	○	○	◉	○	○
Promoting alternatives to animal testing	○	○	○	○	○	○

Please explain your answers

2000 character(s) maximum

As a data generation system, REACH still fails on EDCs:
- substances with low tonnage or intermediate use that may be EDCs are not submitted to sufficient data requirements upon registration
- Current data requirements are not sufficient to provide adequate data on ED properties
- Lack of compliance with the obligation to provide and update data also creates barriers

SVHC identifications need to be quicker, which requires to:
- Use the category of 'suspected EDCs' in the evaluation and identification processes
- systematically apply grouping, as it should have been done for BPA/bisphenols
- the substances already on an EU or national EDC list or regulation should enter the candidate list without further delay
- Delete the equivalent level of concern requirement for EDCs or adopt a guidance dissipating the Member States' concerns about this requirement in light of the recent case-law of the EU Court giving considerable flexibility in its application

Control of EDCs on the candidate list – need to:
- Significantly accelerate the integration to annex XIV and/or XVII
- Systematically consider the adoption of a restriction combined with the entry in annex XIV to avoid the import of products made with SVHCs
- maintain the presumption that EDCs are non-threshold substances, the applicants bearing the burden of rebutting it

Restriction of EDCs not on candidate list – need to:
- Expand the scope of the simplified restriction process (Article 68.2) to EDCs 1 & 2
- Make full use of the precautionary principle
- Ban EDC with derogations opened only for essential uses with minimized exposure or controlled use ensuring negligible exposure of people and the environment over the entire life cycle. Ensure full information of the supply chain and consumers
- Recycled materials shall benefit from a derogation exceptionally, if full traceability allows ensuring that the material will remain in a closed and controlled material loop, for non-sensitive applications

11.d) The regulatory process to identify and control substances with endocrine disrupting properties in **Cosmetics** [2] is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	◉	○
Improving the functioning of the internal market	○	○	○	○	◉	○
Enhancing competitiveness and innovation	○	○	○	○	◉	○
Promoting alternatives to animal testing	○	○	○	○	○	◉

[2] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

Under the current system it is very unlikely that an ingredient with ED properties could be identified as such by the SCCS – a concern explicitly voiced by the SCCS.
Even if it were, SCCS decided to presume that the identification of a safe dose is possible which goes in directly contradiction with common knowledge on EDCs and is a political choice that did not belong to the SCCS.

To adapt the Cosmetic Regulation to the EDC challenge it is indispensable to:
- recognize the policy relevance of using the category of suspected EDCs, indispensable in general but even more acutely in cosmetics considering the ban on animal testing

- apply a rebuttable presumption that EDCs are non-threshold, and place that political choice back in the hand of the risk manager as it should have been from the beginning. The SCCS needs to follow updated implementing guidance.

- When an ingredient is a known or suspected EDCs, it should be automatically banned from cosmetics.
- The Cosmetic Regulation should address possible 'cocktail effects' rather than perform substance-by-substance risk assessment of individual cosmetic ingredients.
- A better coordination with REACH, for example via automatic trigger of entry on the candidate list/ simplified restriction, should happen on the environmental impact of cosmetics

- The migration of EDCs from packaging into the cosmetics should be addressed, for example via a revision of the essential requirements in the packaging and packaging waste directive

Because of all these gaps that undoubtedly create barriers to an effective protection of people from EDCs in cosmetics, the November 2018 Commission review (COM(2018) 739 final) that concluded that the Cosmetics Regulation can address safety concerns related to the use of EDCs needs to be thoroughly re-considered.

11.e) The regulatory process to identify and control substances with endocrine disrupting properties in **Medical Devices** [3] is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting consumers by minimising exposure to endocrine disruptors	○	○	○	○	○	◉
Protecting workers by minimising exposure to endocrine disruptors	○	○	○	○	○	◉
Improving the functioning of the internal market	○	○	○	○	○	◉
Enhancing competitiveness and innovation	○	○	○	○	○	◉
Promoting alternatives to animal testing	○	○	○	○	○	◉

[3] Effects on the environment are regulated via REACH

Please explain your answers

2000 character(s) maximum

The new provisions applying to EDCs improved the framework, but the way they are implemented will determine whether they deliver – for example making sure that the burden of proving whether no alternative is available should remain on the industry, and a failure to bring that proof should lead to not allowing EDCs in the devices.
The system would have been stronger if the new provisions had applied to EDCs irrespective of their concentration in the products, and if a bill of material and bill or substances had been required to enable transparency and the exercise of due diligence in the supply chain.
The criteria that have to be met to justify the presence of EDCs are however sound.

11.f) The regulatory process to control substances with endocrine disrupting properties under the **Water Framework Directive** is effective in:

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Protecting citizens by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○
Protecting wildlife by minimising exposure to endocrine disruptors via the environment	○	○	○	○	◉	○

Please explain your answers

2000 character(s) maximum

The EU-funded SOLUTIONS project just concluded that the WFD and (and other legislations) need to be amended to account for managing the effects of coincidental mixture of water-borne pollutants, as the environmental quality standards defined for single pollutants do not account for mixture risks and do not enable prioritisation of management options
The project further recommends to create proper feedback links between the WFD and chemical legislations such as REACH, PPPR, BPR. It also recommends to have a broader approach to monitoring, not limited to a limited number of individual priority substances
The EEA 2019 state of the environment report identified chemical pollution and emissions of chemicals as one of the areas marked by deteriorating trends and not on track to meet the objectives of the sector by 2030.

The water framework directive fitness check has concluded the legislative framework to be sub-optimal results on the objective of reducing chemical pollution for ex. because of:
- the difficulty in updating the list of priority substances and the fact
- the EQSD and GWD evaluate the risk to people and environment on a substance-by-substance basis not taking into account the combined effects of mixtures

- The chemicals listed as priority substances are a small subset of the thousands of chemicals found in the environment
- being listed as a priority substance or being detected in EU waters does not directly trigger a stricter control of the substance concerned in chemical regulations (the lack of responsiveness between the two sets of regulations was also highlighted as an issue by the chemicals fitness check); being controlled in chemical regulation does not necessarily lead to monitoring provisions in water laws, which misses an opportunity of better enforcement.

The polluter pays should be used to support public authorities prevention and remediation activities, for example for pharmaceuticals pollution.

Aggregated exposure and combined effects

Humans and wildlife can be exposed to the same endocrine disruptor via various sources (**aggregate exposure**) if this substance is present in different types of products.
Humans and wildlife can also be exposed to a combination of multiple endocrine disruptors from one or multiple sources, which may lead to combined effects (**mixture/cocktail effect**). Such effects may include additive and synergistic effects.

12) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Humans are protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources	○	○	○	○	◉	○
Wildlife is protected by the current regulatory framework from the risks associated with the aggregated exposure to one substance with endocrine disrupting properties from all exposure sources	○	○	○	○	◉	○

Please explain your answers and provide examples

1000 character(s) maximum

The failure of the EU regulatory framework to address aggregated exposure to different sources has already been acknowledged many times at EU level.

The regulation of chemical products is entirely focused on the sector-specific use of their ingredients (pesticides, biocides, cosmetics, detergents, food contact material, pharmaceuticals).The regulation of chemicals in consumer products and waste takes into account the exposure within the scope of each piece of legislation only.
Even the horizontal regulation REACH mostly ignores aggregated exposure as registration dossiers have to consider the exposure caused by the uses foreseen by the applicant but not the other sources linked to the activities of other registrants.
To end this fragmentation, the identification of concerns in one sector should trigger automatic consequences in all, information on exposure routes has to be collected/ disclosed and appropriate safety factors need to be adopted

13) Do you agree with the following statements?

	Strongly agree	Moderately agree	Neither agree nor disagree	Moderately disagree	Strongly disagree	Don't know
Humans are protected by the current regulatory framework from the risks associated with the combined exposure to different substances with endocrine disrupting properties (combined effects)	○	○	○	○	◉	○
Wildlife is protected by the current regulatory framework from the risks associated with the combined exposure to different substances with endocrine disrupting properties (combined effects)	○	○	○	○	◉	○

Please explain your answers and provide examples

1000 character(s) maximum

The same remarks developed in answer to question 12 apply here. The Commission committed in 2012, in its Communication on Combination effects of chemicals, to develop by June 2014 technical guidelines to promote a consistent approach to the assessment of mixtures, which has not happened.
The 7 EAP required the Commission to present options to introduce requirements in the relevant pieces of EU chemicals legislation to ensure that the combination and aggregated effects of chemicals are properly and consistently addressed in the risk assessment and risk management process, which the Commission has not delivered. This request has been repeated by the Parliament and the Council since.
The 2017 non-toxic Environment study, the 2020 EEA report of the State of the Environment and the 2019 chemical fitness check all confirm the combined and aggregated exposure gap and the need to close them.

Vulnerable groups

The endocrine system controls a large number of processes in the body throughout life from early stages such as embryonic development, to later ones such as puberty, reproductive life and old age. It controls formation and functions of tissues and organs, as well as homeostasis of physiological processes.

14) Do you think that the following groups are sufficiently protected from exposure to substances with endocrine disrupting properties?

	Yes	No	Don't know
unborn through exposure during pregnancy	○	◉	○
newborn up to the age of 3	○	◉	○
children until puberty	○	◉	○
young persons around the age of puberty	○	◉	○
pregnant women	○	◉	○
adults in general	○	◉	○
people at work	○	◉	○
elderly	○	◉	○
people with illnesses	○	◉	○

Please give examples of regulatory sectors in which a group is not sufficiently protected from exposure to endocrine disruptors and explain why.

2000 character(s) maximum

As demonstrated by the recent Chemicals Fitness Check (COM(2019) 264 final and SWD(2019) 199 final), and the extensive sub-study on vulnerable population of the Non-toxic environment study (NTES), the EU regulatory framework does not consistently and sufficiently protect vulnerable groups.

The NTE study lists the few pieces of EU legislations that refer to vulnerable groups or sub-groups, and that set specific risk assessment or risk management obligations to ensure their protection.

However it also concludes that there is no coherent approach to the definition and protection of vulnerable groups, as well as no clear distinction of the sub-groups of vulnerable population (for ex. for children – foetus, infant, toddler etc) even though they are relevant to determine the exposure (behavior) and the type /intensity of the effect (windows of vulnerability).

In risk assessment and risk management, the average adult remains the common point of reference to estimate exposure and safe dose.

This problem, that affects the regulation of all hazardous chemicals, is particularly acute for endocrine disruptors considering the irreversibility of their effects as well as their increased potency during specific windows of exposure such as early pregnancy. The need to adapt the list of chemicals controlled under the drinking water directives is a typical example.

In addition to a failure to specifically address vulnerable groups in risk assessment and risk assessment in

existing regulations, the regulatory framework suffers from blatant gaps in some sectors of high relevance for vulnerable groups, such as:
- indoor pollution, particularly in buildings dedicated to vulnerable groups (nurseries, schools)
- childcare equipment, furniture. An example of inconsistency is the ban of certain phthalates, not allowed in toys under REACH but allowed in other products such as carpets, textiles or furniture to which children can be exposed to.
- food contact material

Data requirements and available regulatory test methods

Several EU regulations require registrants or applicants to perform some tests on the toxicity of their substance. These tests should be run according to validated test methods that are accepted by the authorities (Test Guidelines adopted at international level such as the OECD, or methods laid down in the Commission Regulation (EC) 440/2008 on test methods). Several of these tests can be used to identify endocrine disruptors.

15) Are available regulatory **tests** sufficient **to identify endocrine disruptors** for humans (including vulnerable groups) as well as wildlife?

- ○ Yes
- ◉ No

Which tests should be developed?

1000 character(s) maximum

16) Are current provisions for **data requirements** laid down in relevant legislation (REACH, Biocidal Products Regulation, Plant Protection Products Regulation) sufficient **to identify endocrine disruptors** for humans (including vulnerable groups) as well as wildlife?

- ○ Yes
- ◉ No

Please specify what requirements you would add or modify in each piece of legislation.

1000 character(s) maximum

As demonstrated by the second REACH review, several REACH annexes need to be updated so that they oblige the industry to provide data able to support the identification of endocrine disruptors cat 1 and 2 – which is not the case today.

Requirements for low volume substances should also be introduced to reduce the data gap on the estimated 70 000 substances on the market that enter the exposome with poor characterization for their hazards and exposures (see EEA SOER p 239).

Finally, the competent authorities should systematically consider both industry data and relevant academic research, if it is independent from vested interest and even when they do not follow OECD guidelines and GLP

The on-going efforts to update the data requirements under REACH, BPR and PPPR should be accelerated and not wait for the results of the fitness check

17) Considering the information requirements of REACH, the Biocidal Products Regulation and the Plant Protection Products Regulation, do you think the likelihood of identifying a substance as an endocrine disruptor is lower under one of these regulations compared to the others?

- (●) Yes
- ( ) No

Please explain your answer and provide examples.

1000 character(s) maximum

18) Do you have any further comments on available regulatory test methods and data requirements under REACH, the Biocidal Products Regulation, the Plant Protection Products Regulation, and other sector specific legislation?

2000 character(s) maximum

It is indispensable to recognise the regulatory relevance of the category of suspected EDCs in order to enable an effective identification system under these regulations considering that even with fully updated data requirements, blind spots will still remain as available test methods are not sufficient

Precise guidance to inform on the obligation to use the existing relevant test methods under the Detergent Regulation must be adopted

Regulatory testing and animal welfare

Data generation according to standard information requirements is expensive, time consuming and requires the use of animals. The recently adopted criteria for identifying of endocrine disruptors require information on endocrine activity and adverse effects.

19) Do you agree with the following statement?
In vitro and/or *in silico* methods are not used systematically enough to prioritise further investigations.

- ( ) Strongly agree
- ( ) Moderately agree
- ( ) Neither agree nor disagree
- ( ) Moderately disagree
- ( ) Strongly disagree
- ( ) Don't know

Please explain your answer.

1000 character(s) maximum

Regulations requiring testing for endocrine disrupting properties of a substance (Biocidal Products Regulation, Plant Protection Products Regulation, REACH) specifically require the use of vertebrate animals to be minimised, in accordance with Directive 2010/63/EU on the protection of animals used for scientific purposes.

20) In your opinion, is the impact of assessing chemicals for endocrine disrupting properties on animal welfare minimised in the EU?

- (●) Not at all
- ( ) Insufficiently minimised
- ( ) Minimised to the extent possible
- ( ) Don't know

21) Do you have recommendations on how to further minimise the impact of assessing chemicals for endocrine disrupting properties on animal welfare?

1000 character(s) maximum

A system where tests are performed by independent laboratories, supervised and ordered by EU agencies and paid via a fund to which all relevant industries contribute would avoid useless repetition of animal testing by making the data public.
Making sure that the identification of a substance as an EDC in a specific sector automatically triggers hazard-based management measures in all other relevant sectors would avoid duplications.
Three other general ways to reduce animal testing would be to:
- fully integrate the conclusions of academic research independent from vested interest (even non OECD guidelines and GLP)
- ensure that the tests performed by industry follow the most sensitive and relevant test methods, to avoid animal testing that would in any case be blind to the properties of interest
- recognize in all sectors the policy relevance of suspected EDCs, to avoid wasting resources in trying to achieve a level of evidence that is not needed

Effectiveness of regulatory procedures

The following sectors are regulated via sector-specific legislation as well as by horizontal/other legislation (e. g. REACH, Biocidal Products Regulation, CLP Regulation).

22) Are you aware of issues that result from the lack of specific provisions for **identifying** endocrine disruptors in sector-specific legislation for the following areas:

	Yes	No
Workers protection	(●)	( )
Toys	(●)	( )
Detergents	(●)	( )
Fertilisers	(●)	( )
Electrical and electronic equipment	(●)	( )
Food contact materials	(●)	( )
Food additives	(●)	( )

Cosmetics	◉	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	○	◉
Human and veterinary pharmaceuticals (only for effects on the environment)	◉	○
Water	◉	○
Waste/recycling	◉	○
Other (please specify)	○	○

Please explain your answers, including the consideration of sector-specific interconnections with horizontal legislation (e.g. REACH).

1000 character(s) maximum

REACH candidate list is currently the only horizontal identification system able to capture EDCs. However, only the ecolabel Regulation and the new medical devices/in vitro diagnostic medical devices directives use it to identify the hazardous substances within their scope.

In this context, the identification of EDCs relies entirely:
- On substance testing for the few regulations that organize it (chemical products, chemical in some products). Specific provisions on EDCs are needed to make sure that EDC properties are one of the properties that industry has to test for.
- On sector-specific list of hazardous substances for all the others (consumer product, waste, waster), that are limited and outdated when it comes to EDCs.
Specific provisions are needed to 1) refer to an existing or new EDC horizontal identification system 2) trigger the revision of outdated internal lists in light of existing EU and national lists/regulations

23) Are you aware of issues that result from the lack of specific provisions for **managing** endocrine disruptors in sector-specific legislation for the following areas:

	Yes	No
Workers protection	○	◉
Toys	◉	○
Detergents	◉	○
Fertilisers	◉	○
Electrical and electronic equipment	◉	○
Food contact materials	◉	○
Food additives	◉	○
Cosmetics	◉	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	○	◉
Human and veterinary pharmaceuticals (only for effects on the environment)	◉	○
Water	◉	○

Waste/recycling	◉	○
Other (please specify)	◉	○

Please explain your answers, including the consideration of sector-specific interconnections with horizontal legislation (e.g. REACH).

1000 character(s) maximum

EDCs should be prohibited with derogations allowed only for essential uses (see Cousins et all, 2019) with minimized exposure.
REACH restrictions would be an efficient tool to apply this logic horizontally, if specific provisions extend art 68.2 to EDCs
Sectoral legislations need specific EDC provisions to apply the regulatory approach described above. The regime applied to most Regulations to manage the adverse effects of the substances they identify as hazardous is not adapted to EDCs: identification of a “safe dose” (IED, FCM), derogations allowed even for non-essential use (cosmetics) and even for the regulations supposed to be the most protective, ban over a set concentration (Toys, Medical Devices)
The IED Directive and the FCM Regulation need urgent revision. Regulation is needed for indoor EDC pollution (carpet, construction materials, furniture) and sanitary products. Waste and water legislations also need special management of EDCs (remediation, polluter pays, etc.)

24) In your view, on which areas should market surveillance authorities focus their activities to effectively enforce chemical safety of products as regards endocrine disruptors?

	Yes	No	Don't know
Plant Protection Products	◉	○	○
Biocidal products	◉	○	○
General chemicals	◉	○	○
Toys	◉	○	○
Detergents	◉	○	○
Fertilisers	◉	○	○
Electrical and electronic equipment	◉	○	○
Food contact materials	◉	○	○
Food additives	◉	○	○
Cosmetics	◉	○	○
Medical devices and *in vitro* diagnostic medical devices (only for effects on the environment)	○	○	◉
Human and veterinary pharmaceuticals (only for effects on the environment)	○	○	◉
Waste/recycling	◉	○	○
Other (please specify)	◉	○	○

Other:

50 character(s) maximum

On line sales

Adequacy of legislation to address needs and concerns on endocrine disruptors

In 1999 the European Commission published a Community strategy on endocrine disruptors, reflecting public concerns that these substances might cause diseases/disorders in humans and affect wildlife populations and biodiversity. Diseases/disorders in humans that are endocrine-related (i.e. via effect on the endocrine system) might result from a combination of factors such as genetic origin, diet, lifestyle, exposure to endocrine disruptors and other chemical stressors. Effects on wildlife populations and biodiversity might be caused by a combination of factors such as habitat loss, climate change, exposure to endocrine disruptors and other chemical stressors.

30) To what extent do you think exposure to endocrine disruptors is contributing to the **increase in endocrine-related human diseases/disorders**, in the EU, in comparison with other factors?

- (●) To a significant extent
- ( ) Not to a significant extent
- ( ) Not at all
- ( ) Don't know

31) To what extent do you think exposure to endocrine disruptors is contributing to the **decrease in aquatic and terrestrial biodiversity** in the EU, in comparison with other factors?

- (●) To a significant extent
- ( ) Not to a significant extent
- ( ) Not at all
- ( ) Don't know

The 1999 Community strategy highlighted the need for research and development of new tools to understand the mechanisms of endocrine disruption.

32) Is the regulatory framework flexible enough to take into account new scientific information and methods in the assessment of endocrine disrupting properties (e.g. new toxicological tests, (bio)monitoring data, (eco)epidemiology)?

- ( ) Yes
- (●) No

Please explain your answer with examples for specific regulated areas.

1000 character(s) maximum

Lists of approved test methods in EU law are useful but may slow the uptake of the newest methods down. Such lists could be improved by an automatic trigger for revision or by a general obligation to apply the most sensitive and up-to-date test methods
Most EU laws contain revision trigger in case of new scientific information, but this possibility must become an obligation for the competent authority – often the Commission – to initiate a review of the positive or negative lists/authorisation in case of early warnings of hazards and to check at least bi-annually for early

warnings.
Member States and EU institutions are legally allowed, but should be obliged to, systematically integrate independent research in their appreciation of the need for stricter control of EDCs. Competent authorities must break from their current reluctance to use non-OECD/GLP independent research to embrace all relevant scientific data as it is the only way to react on time to early warnings of hazards

33) Do you have any further comments on the adequacy of legislation to address societal needs and concerns on endocrine disruptors?

2000 character(s) maximum

The concept of essential use, developed for substances that must be treated as non-threshold, has an important role to play in the regulation of EDCs.
It is a tool to run efficiently and fairly the difficult process of phasing out these substances used for a wide range of applications. The management of EDCs should rely on the principle of prohibition with sector specific derogations, opened to essential uses with minimized exposure. This approach would lead to the strictest prohibition in sectors such as Toys and Cosmetics, and to the existence of legitimate derogation in sectors such as medical devices.
This concept focuses on what economic activities/profits are worth turning away from in order to create opportunities for safer and more sustainable ones, while maintaining the well-beings of society members and ensuring a fair transition, particularly for vulnerable groups.
A core societal need is to relieve citizens, in particular vulnerable groups such as expectant couples, from the concern of protecting oneself against a risk that is omnipresent. In that regard, information on the presence of EDCs in products can never replace a prohibition that help citizens trust the products on the EU market.
The compliance with EU law must become a brand seen by EU citizens as a trustworthy guarantee of safety.
Finally, the education and medical community must help raise awareness on EDCs risks and ways to avoid them.

Civil society organisation should have been allowed to answer question 29 as it concerns societal benefits.
For EDC, as non-threshold substances, it should be assumed that the benefits of minimizing the exposure overweigh the costs, and not, as in the context of a CBA, that the benefits may not justify the costs.
The only legitimate economic analysis must aim at finding the most cost efficient ways to reduce the emissions via a Cost effectiveness analysis (SEAC/24/2014/04, agreed for PBT and vPvB).

Added value of EU level intervention

There have been instances where Member State authorities have taken unilateral action on endocrine disruptors before a decision has been taken at the EU level. For example, in October 2012, the French authorities introduced a ban of Bisphenol A in all Food Contact Materials, applicable from July 2015.

34) Do you think:

- ○ This is not justifiable – decisions should be taken at EU level and all citizens of the EU should be protected in an equal way, while preserving the integrity of the single market.
- ◉ This is justifiable, but it should be followed by an EU wide action to preserve the integrity of the single market.
- ○ This is justifiable in some cases – protection of human health or the environment is more important than preserving the integrity of the single market.
- ○ This is justifiable – endocrine disruptors should not be regulated at EU level.

Under which circumstances do you think that a decision at national level would be justifiable?

1000 character(s) maximum

Member States should always be allowed to take unilateral action when they have evidence that the harmonized level of protection set by EU law is not sufficient, or when specific national circumstances justify it. The convenience of harmonization must never be used as a reason to drag down the level of environmental or health protection. On the contrary, Member States experimentation may conduce to insights that will usefully inform potential EU action.
When a Member State takes such action, the Commission should be obliged to review the EU wide measures in order to guarantee an equal protection to all EU citizens, within a short pre-defined timeframe.

36) Do you have any further comments on the added value of regulating endocrine disruptors at EU level?

1000 character(s) maximum

The EU promised to adopt concrete measures that will minimize the exposure to EDCs and will address aggregated and combined exposure a long time ago.
Delivering those measures, achieving these objectives, are now a pre-condition to the Commission's capacity to be trusted as the defender of the public interest.
Beyond deserving trust, delivering those measures is also a pre-condition to the success of the Green Deal in general and of the Circular economy, Biodiversity, Farm to Fork and zero pollution strategies in particular.
The Commission’s President rightly identified the fight against pollution as a popular political goal and a path towards increased well-being combining innovation, wealth and sustainability. With the NTE study, the REACH review, the chemicals, PPPR, toys (etc.!) refits and now the EDC one the Commission has more than enough data to act – the time is now for concrete measures, not for yet another plan promising the same deliverables than ten years ago

Useful links

European Commission central information portal on endocrine disruptors (https://ec.europa.eu/info/policies/endocrine-disruptors_en)

Harmful chemicals endocrine disruptors, review of EU rules (https://ec.europa.eu/info/law/better-regulation/initiati/ares-2019-2470647_en)

Contact

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